

**VIA FEDERAL EXPRESS**

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February 19, 2004

Examiner Minh Tam B. Davis  
Art Unit 1642  
U.S. Patent and Trademark Office  
Remsen Bldg.  
400 Dulany Street  
Alexandria, VA 22313

Re:    Applicant:        Bernard Lethe, et al.  
      Serial No.:        09/341,829  
      Confirmation No.: 5643  
      Filing Date:        October 18, 1999  
      For:                LAGE-1 TUMOR ASSOCIATED NUCLEIC ACIDS

Dear Examiner Davis:

Enclosed please find a copy of the PTO-1449 Form and references for the above-identified case.

Also enclosed is a copy of a Supplemental Information Disclosure Statement, PTO-1449 Form and references cited. This IDS has also been sent via Express Mail.

If you have any questions or concerns, please do not hesitate to contact me.

Respectfully submitted,

WOLF, GREENFIELD & SACKS, P.C.

  
John R. Van Amsterdam  
Reg. No. 40,212

JRV/jmw  
Enclosures

<b>ORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		APPLICATION NO.: 09/341,829		ATTY. DOCKET NO.: L0461.70066US00		
		FILING DATE: October 18, 1999		CONFIRMATION NO.: 5643		
		APPLICANT: LETHE et al.				
		GROUP ART UNIT: 1642		EXAMINER: Minh Tam B. Davis		
Sheet	1	of	1			

#### FOREIGN PATENT DOCUMENTS

Examiner's initials†	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	CA	2346942	A1	Boehringer Ingelheim International GmbH	04-27-2000	Y
	B2	EP	1001022	A1	Boehringer Ingelheim International GmbH	05-17-2000	Y
	B3	EP	1121435	A1	Boehringer Ingelheim International GmbH	08-08-2001	Y
	B4	JP	2002527109T	A1	Boehringer Ingelheim International GmbH	08-27-2002	Y
	B5	WO	0023584	A1	Boehringer Ingelheim International GmbH	04-27-2000	Y

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials†	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	SHARMA P. et al., "Frequency of NY-ESO-1 and LAGE-1 expression in bladder cancer and evidence of a new NY-ESO-1 T-cell epitope in a patient with bladder cancer," <i>Cancer Immun.</i> , December 18, 2003; 3:19.	Y
	C2	ODUNSI K. et al., "NY-ESO-1 and LAGE-1 cancer-testis antigens are potential targets for immunotherapy in epithelial ovarian cancer," <i>Cancer Res.</i> , September 15, 2003; 63(18):6076-83.	Y
	C3	USENER D. et al., "Seroreactivity against MAGE-A and LAGE-1 proteins in melanoma patients," <i>Br J Dermatol.</i> , August 2003; 149(2):282-8.	Y
	C4	SLAGER E.H. et al., "CD4+ Th2 cell recognition of HLA-DR-restricted epitopes derived from CAMEL: a tumor antigen translated in an alternative open reading frame," <i>J Immunol.</i> , February 1, 2003; 170(3):1490-7.	Y
	C5	RIMOLDI D. et al., "Efficient simultaneous presentation of NY-ESO-1/LAGE-1 primary and nonprimary open reading frame-derived CTL epitopes in melanoma," <i>J Immunol.</i> , December 15, 2000; 165(12):7253-61.	Y
	C6	MANDIC M. et al. "The alternative open reading frame of LAGE-1 gives rise to multiple promiscuous HLA-DR-restricted epitopes recognized by T-helper 1-type tumor-reactive CD4+ T cells," <i>Cancer Res.</i> , October 1, 2003; 63(19):6506-15.	Y
	C7	AARNOUDSE C.A., "Interleukin-2-induced, melanoma-specific T cells recognize CAMEL, an unexpected translation product of LAGE-1," <i>Int J Cancer.</i> , July 30, 1999; 30;82(3):442-8.	Y
	C8	LETHE B. et al, "LAGE-1, a new gene with tumor specificity," <i>Int J Cancer.</i> , June 10, 1998; 76(6):903-8.	Y

EXAMINER	DATE CONSIDERED
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†EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 09/341,829		DOCKET NO.: L0461.70066US00	
				FILING DATE: October 18, 1999		CONFIRMATION NO.: 5643	
				APPLICANT: LETHE et al.			
				GROUP ART UNIT: 1642		EXAMINER: Minh Tam B. Davis	
Sheet	1	of	1				

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	6,140,050	B1	Sahin, et al.	10/31/2000
	A2	6,251,603	B1	Jäger, et al.	06/26/2001
	A3	6,252,052	B1	Stockert, et al.	06/26/2001
	A4	6,274,145	B1	Chen, et al.	08/14/2001
	A5	6,338,947	B1	Sahin, et al.	01/15/2002
	A6	6,417,165	B1	Valmori, et al.	07/09/2002
	A7	6,525,177	B2	Stockert, et al.	02/25/2003
	A8	6,605,711	B1	Valmori, et al.	08/12/2003
	A9	6,689,742	B1	Cerundolo, et al.	02/10/2004
	*A10	5,342,774		Boon, et al.	08/30/1994
	*A11	5,405,940		Boon, et al.	04/11/1995

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials†	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	*B7	WO	96/10577		Ludwig Inst. for Cancer Research	04/11/1996	Y
	B8	WO	98/14464		Ludwig Inst. for Cancer Research		

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials†	Cite No.	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C9	Chen, et al., "A testicular antigen aberrantly expressed in human cancers detected by autologous antibody screening," Proc. Nat'l. Acad. Sci. USA Vol. 94 pgs.:1914-1918 (March 1997)	
	C10	Hillier, EMBL Database, Accession No. AA634317 (Oct. 1997)	
	*C11	Traversari, et al., Immunogenetics 35:145 (1992)	
	*C12	Van der Bruggen, et al. Science 254:1643-1647 (1991)	
	*C13	Rammensee, et al., Immunogenetics 41:178-228 (1995)	
	*C14	Van den Eynde, et al., Curr. Opinion in Immun. 7:674-681 (1995)	
	*C15	De Plaen et al., Immunogenetics 40:360-369, (1994)	
	*C16	Coulie et al., Stem Cells 13:393-403, (1995)	
	*C17	Hubank and Schatz, Nucl. Acids Res. 22:5640, (1994)	

EXAMINER	DATE CONSIDERED
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†EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. 08/791,495, filed 01/27/1997, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

Serial No 09/341,829 File No. LO461,70066US00 By: JRV/jmw  
Title: LAGE-1 Tumor Associated Nucleic Acids  
Application of \_\_\_\_\_ WGS Date: \_\_\_\_\_

The U.S. PTO Mail Room acknowledges receipt of the following on the date stamped hereon:

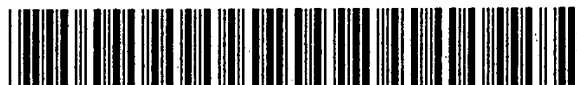
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Express Mail Label No. EV292458356US  
☐ Patent Application  
    ☐ Non-provisional ☐ Provisional  
    Incl. \_\_\_\_\_ pages, ( \_\_\_\_\_ pgs) Specification,  
    ( \_\_\_\_\_ pgs) Abstract, ( \_\_\_\_\_ pgs) Claims ( \_\_\_\_\_ # claims)  
☐ Design Patent Application  
☐ Declaration(s) \_\_\_\_\_  
☐ Drawings \_\_\_\_\_ Sheet(s) (FIGS. \_\_\_\_\_)  
    ☐ Formal ☐ Informal  
☐ Utility Patent Application Transmittal  
☐ Fee calculation sheet (x2)  
☐ CPA Transmittal  
☐ Verified Statement claiming small entity status  
☐ Request for Approval and Entry of Formal Drawings

- ☒ Provisional Application Cover Sheet  
☒ Multiple Dependent Claim Fee Sheet  
☒ Inf. Discl. Statement, PTO Form 1449  
☒ References Cited  
Priority Document(s) # \_\_\_\_\_  
Copy of Notice to File Missing Parts  
Amendment/Response  
Petition for Ext. of Time (x2)  
Issue Fee Transmittal  
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*John R. Van Amsterdam*  
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**Date of Deposit: February 19, 2004**

DOCKET NO.: L0461.70066US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bernard Lethe, et al.  
Serial No.: 09/341,829  
Confirmation No.: 5643  
Filing Date: October 18, 1999  
For: LAGE-1 TUMOR ASSOCIATED NUCLEIC ACIDS

Examiner: Minh Tam B. Davis  
Art Unit: 1642

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:


Transmitted herewith are the following documents:

- ☒ **Supplemental Information Disclosure Statement**
- ☒ **Form PTO-1449 with References Cited**
- ☒ **Return Receipt Postcard**

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617)720-3500, Boston, Massachusetts.

No fee is enclosed. If a fee is necessary, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
**Bernard Lethe et al., Applicants**

By:   
John R. Van Amsterdam, Reg. No. 40,212  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No. L0461.70066US00  
Date: February 19, 2004  
xNDDx

*Express Mail Label No.: EV 292458356 US*

*Date of Deposit: February 19, 2004*

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bernard Lethe, et al.  
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Examiner: Minh Tam B. Davis  
Art Unit: 1642

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

Compliance with 37 C.F.R. § 1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action after the filing of a request for continued examination under 37 C.F.R. §1.114.

No fee or certification is required.

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

The following are remarks concerning the other information cited:

REMARKS

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. § 102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Bernard Lethe et al., Applicants*

By:   
John R. Van Amsterdam, Reg. No. 40,212  
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600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No.: L0461.70066US00

Date: February 19, 2004

**xNDDx**